

106TH CONGRESS  
2D SESSION

# S. 2743

To amend the Public Health Service Act to develop an infrastructure for creating a national voluntary reporting system to continually reduce medical errors and improve patient safety to ensure that individuals receive high quality health care.

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## IN THE SENATE OF THE UNITED STATES

JUNE 15, 2000

Mr. KENNEDY (for himself, Mr. DODD, and Mrs. MURRAY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Public Health Service Act to develop an infrastructure for creating a national voluntary reporting system to continually reduce medical errors and improve patient safety to ensure that individuals receive high quality health care.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Voluntary Error Re-  
5       duction and Improvement in Patient Safety Act”.

1 **SEC. 2. PURPOSE.**

2 It is the purpose of this Act to establish a national  
3 voluntary system to continually reduce medical errors, and  
4 the harm that results from such errors, and improve pa-  
5 tient safety to ensure that individuals receive the highest  
6 quality health care.

7 **SEC. 3. REDUCING MEDICAL ERRORS AND IMPROVING PA-**  
8 **TIENT SAFETY.**

9 Title IX of the Public Health Service Act (42 U.S.C.  
10 299 et seq.) is amended—

11 (1) by redesignating part C as part D;

12 (2) by redesignating sections 921 through 928,  
13 as sections 931 through 938, respectively;

14 (3) in section 938(1) (as so redesignated), by  
15 striking “921” and inserting “931”; and

16 (4) by inserting after part B the following:

17 **“PART C—REDUCING MEDICAL ERRORS AND**  
18 **IMPROVING PATIENT SAFETY**

19 **“SEC. 921. DEFINITIONS.**

20 “In this part:

21 “(1) ACCREDITING ORGANIZATION.—The term  
22 ‘accrediting organization’ means a national, non-  
23 profit organization that—

24 “(A) accredits health care professionals;

25 and

1           “(B) is recognized as an accrediting entity  
2           by Federal or State law or by a Federal or  
3           State agency that regulates health care profes-  
4           sionals or health care organizations.

5           “(2) ADVERSE SAFETY EVENT.—The term ‘ad-  
6           verse safety event’ means an occurrence that is di-  
7           rectly associated with medical care or services pro-  
8           vided by a health care organization that results, or  
9           could result, in an accident, injury, or illness.

10          “(3) BEST PRACTICE.—The term ‘best practice’  
11          with respect to the provision of health care or serv-  
12          ices, means—

13               “(A) an excellent or optimal action, con-  
14               duct, or procedure, based on sound science; or

15               “(B) an excellent or optimal level of per-  
16               formance, based on sound science.

17          “(4) CENTER.—The term ‘Center’ means the  
18          Center for Quality Improvement and Patient Safety  
19          established under section 922.

20          “(5) DIRECTOR.—The term ‘Director’ means  
21          the Director of the Agency for Healthcare Research  
22          and Quality.

23          “(6) HEALTH CARE ORGANIZATION.—The term  
24          ‘health care organization’ means an entity that pro-  
25          vides health care services in the ordinary course of

1 business or practice of a profession, pursuant to a  
2 license, certification, accreditation, or other legal au-  
3 thorization. Such term shall include hospitals, phar-  
4 macies, health clinics, long-term care facilities, inter-  
5 mediate care facilities, home health agencies, hospice  
6 programs, residential treatment centers, physicians'  
7 offices, and the officers, employees, and agents of  
8 such entities (such as physicians, nurses, phar-  
9 macists, interns, residents, and other health care  
10 professionals).

11 “(7) HEALTH CARE PROFESSIONAL.—The term  
12 ‘health care professional’ means an individual who is  
13 licensed or otherwise authorized by State law to pro-  
14 vide health care services in that State.

15 “(8) HUMAN FACTORS.—The term ‘human fac-  
16 tors’ with respect to health care means human char-  
17 acteristics derived from the study of the interaction  
18 of humans with systems, products, and the environ-  
19 ment. Such characteristics may be derived through  
20 the development of psychological principles and  
21 knowledge in areas such as perception, cognition,  
22 and decisionmaking. Such term includes biomedical  
23 and psychosocial considerations, human engineering,  
24 personnel selection, training, life support, job per-  
25 formance, and human performance evaluation.

1 “(9) MEDICAL ERROR.—The term ‘medical  
2 error’ with respect to the provision of health care or  
3 services, means—

4 “(A) the failure of a planned action to be  
5 completed as intended; or

6 “(B) the use of a wrong plan to achieve a  
7 desired result.

8 “(10) SURVEILLANCE SYSTEM.—The term  
9 ‘Surveillance System’ means the National Patient  
10 Safety Surveillance System established under section  
11 925.

12 “(11) STATE.—The term ‘State’ means each of  
13 the 50 States, the District of Columbia, the Com-  
14 monwealth of Puerto Rico, the United States Virgin  
15 Islands, Guam, American Samoa, and the Common-  
16 wealth of the Northern Mariana Islands.

17 “(12) VOLUNTARY REPORTING SYSTEM.—The  
18 term ‘Voluntary Reporting System’ means the Na-  
19 tional Patient Safety Reporting System established  
20 under section 924.

21 **“SEC. 922. CENTER FOR QUALITY IMPROVEMENT AND PA-**  
22 **TIENT SAFETY.**

23 “(a) ESTABLISHMENT.—There is established within  
24 the Agency for Healthcare Research and Quality an office  
25 to be known as the Center for Quality Improvement and

1 Patient Safety, which shall be headed by an individual to  
 2 be appointed by the Director. The Secretary shall carry  
 3 out this part acting through the Director.

4 “(b) PURPOSE.—The purpose of the Center is to pro-  
 5 mote patient safety through the establishment of an infor-  
 6 mation infrastructure and evidence base for patient safety  
 7 to permit health care professionals and organizations to  
 8 take a more strategic approach to reducing medical errors  
 9 and improving patient safety. In carrying out the purpose  
 10 of this subsection the Director shall—

11 “(1) direct the efforts of the Center across all  
 12 types of health care organizations, health care pro-  
 13 fessionals, and patients;

14 “(2) take into consideration differences between  
 15 types of health care organizations and make rec-  
 16 ommendations for best practices in a manner that  
 17 takes into consideration such differences;

18 “(3) collect and analyze existing information on  
 19 the causes of medical errors and evidence-based rec-  
 20 ommendations to reduce such errors; and

21 “(4) obtain input from, and consult with, enti-  
 22 ties as provided for in subsection (c).

23 “(c) INPUT AND CONSULTATION.—To carry out the  
 24 purpose described in subsection (b), the Director shall—

1           “(1) obtain input from a wide range of public  
 2           and private sources, including Federal as well as  
 3           State governmental entities, including the Centers  
 4           for Disease Control and Prevention, the Food and  
 5           Drug Administration, the National Institutes of  
 6           Health, the Health Care Financing Administration,  
 7           the Department of Veterans Affairs, the Department  
 8           of Defense, State departments of health, State li-  
 9           censing boards, organizations representing health  
 10          care professionals and health care organizations,  
 11          purchasers, industry, consumer groups, and other  
 12          public, private, and public-private organizations and  
 13          alliances that address quality in health care; and

14          “(2) consider input from relevant disciplines  
 15          and industries that have a demonstrated experience  
 16          with proven safety initiatives, such as the aviation  
 17          industry, industrial engineering, anesthesiology, and  
 18          psychology.

19       **“SEC. 923. GENERAL ACTIVITIES.**

20          “(a) IN GENERAL.—The Center, and other compo-  
 21          nents of the Agency for Healthcare Research and Quality  
 22          as the Director determines to be appropriate, shall—

23          “(1) serve as a central, publicly accessible clear-  
 24          inghouse for information concerning patient safety,  
 25          including data collected through the Voluntary Re-

1        reporting System and the Surveillance System, and in-  
2        formation about the causes of medical errors and  
3        best practices to prevent or minimize medical errors  
4        and injuries that may result from such errors;

5            “(2) administer the National Patient Safety Re-  
6        porting System under section 924;

7            “(3) administer the National Patient Safety  
8        Surveillance System under section 925;

9            “(4) conduct, support, and coordinate the anal-  
10       ysis of data collected through the Voluntary Report-  
11       ing System in conjunction with multi-disciplinary  
12       panels of experts selected from the public and pri-  
13       vate sector;

14           “(5) conduct and support research on the  
15       causes of and best practices to prevent or minimize  
16       medical errors;

17           “(6) support the Patient Safety Centers of Im-  
18       provement established under section 926 to develop  
19       effective and fiscally responsible best practices to ad-  
20       dress critical patient safety challenges, including de-  
21       signing management and information systems that  
22       optimize patient safety;

23           “(7) obtain and provide evidence-based informa-  
24       tion to guide in the development and continuous im-  
25       provement of best practices;

1           “(8) educate the public and the health care  
2       community concerning the existence and causes of  
3       medical errors, the lessons learned, outcomes meas-  
4       ures, and best practices with respect to medical er-  
5       rors;

6           “(9) promote the universal acknowledgment,  
7       adoption, and implementation of best practices to  
8       promote more efficient, effective, and safe health  
9       care systems throughout the Nation; and

10          “(10) carry out other functions determined ap-  
11       propriate by the Secretary to fulfill the purpose of  
12       the Center.

13          “(b) 3-YEAR REQUIREMENTS.—Not later than 3  
14       years after the date on which the Center is established,  
15       the Director shall—

16               “(1) based on expert opinion and a review of  
17       the current evidence relating to medical errors, de-  
18       velop a limited, achievable set of high-priority goals  
19       for improving patient safety;

20               “(2) assess the progress made in achieving the  
21       goals developed under paragraph (1) by compiling  
22       aggregate information from Federal, State, and  
23       other adverse event or error reporting systems,  
24       health care organizations, and other sources;

1           “(3) for purposes of making the assessments  
2           under paragraph (2), periodically conduct a survey  
3           or review of representative health care organizations  
4           with respect to the progress of such organizations in  
5           meeting the goals established under paragraph (1);

6           “(4) develop and provide support for a research  
7           agenda as described in subsection (c), which may in-  
8           clude the use of existing data sources, such as health  
9           claims databases, if appropriate;

10          “(5) in accordance with subsection (d), evaluate  
11          existing, and develop evidence for new best practices  
12          and tools for improving and protecting patient safety  
13          in key processes, including clinical, managerial, and  
14          informational support systems for—

15               “(A) medication systems (from prescribing  
16               to administering);

17               “(B) operating rooms, surgical procedures,  
18               and surgical care (including pre-operative and  
19               post-operative care);

20               “(C) emergency departments;

21               “(D) the management of diagnostic tests,  
22               screening, and information;

23               “(E) intensive care units, including neo-  
24               natal and pediatric intensive care units;

1           “(F) the care of frail elderly (such as care  
2           after falls and for decubitus ulcers);

3           “(G) the use of simulation and simulators  
4           in health care training;

5           “(H) team training and crew resource  
6           management applications in health care; and

7           “(I) home health care services;

8           “(6) develop instructional methods, demonstra-  
9           tion projects, and technical support projects to en-  
10          sure the widespread implementation of the best  
11          practices and tools developed under this subsection;

12          “(7) provide technical support to health care or-  
13          ganizations to enable such organizations to provide  
14          for internal quality improvement demonstration  
15          projects to improve patient safety;

16          “(8) develop tools and methods for educating  
17          consumers and purchasers about patient safety;

18          “(9) facilitate technology transfer from indus-  
19          tries that have succeeded in reducing errors and im-  
20          proving safety within their industry;

21          “(10) increase the understanding of health care  
22          organizations, health care professionals, and the  
23          public concerning the use of information technology  
24          to improve patient safety (such as automated drug  
25          order entry systems and reminder systems);

1           “(11) increase the understanding of health care  
2           organizations, health care professionals, and the  
3           public concerning medical errors in different settings  
4           (such as in ambulatory or home care settings) and  
5           among different populations (including individuals  
6           with disabilities and other vulnerable populations  
7           such as children and the elderly);

8           “(12) establish baseline rates of specific types  
9           of medical errors and monitor trends in such rates,  
10          as appropriate;

11          “(13) establish Centers of Patient Safety Im-  
12          provement as provided for in section 926;

13          “(14) develop or support the development of  
14          tools to objectively measure the impact of best prac-  
15          tices on patient safety and to measure progress to-  
16          wards implementing best practices;

17          “(15) establish the National Patient Safety Re-  
18          porting System;

19          “(16) establish the National Patient Safety  
20          Surveillance System;

21          “(17) research and analyze existing State man-  
22          datory reporting systems;

23          “(18) disseminate information to health care  
24          organizations, health care professionals, and other  
25          interested parties concerning the causes of medical

1 errors, the lessons learned with respect to such er-  
2 rors, outcomes measures, and best practices;

3 “(19) develop and disseminate educational ma-  
4 terial to the public concerning the manner in which  
5 medical errors may be avoided and the manner in  
6 which the public can take a more active role in their  
7 health care;

8 “(20) collaborate with health care professional  
9 associations, licensing bodies, and other related or-  
10 ganizations in the provision of training in medical  
11 error reduction and prevention, and patient safety;  
12 and

13 “(21) develop an awards or incentive program  
14 for health care professionals and health care organi-  
15 zations that develop effective methods to enhance  
16 patient safety.

17 “(c) RESEARCH.—

18 “(1) PROCESS.—In carrying out subsection  
19 (b)(4), the Director shall establish a formal process  
20 to gather information on priorities, methodologies  
21 and approaches for medical errors and patient safety  
22 research. In gathering such information, the Direc-  
23 tor shall ensure that input is obtained from a wide  
24 range of individuals and organizations who will use

1 and can benefit from the availability of such infor-  
2 mation.

3 “(2) OTHER INDUSTRIES.—In carrying out this  
4 subsection, the Director shall consider the experi-  
5 ences of other industries in reducing errors within  
6 such industries and the processes that such indus-  
7 tries employ to reduce errors.

8 “(3) ISSUES.—The issues to be addressed with  
9 respect to the research to be conducted and sup-  
10 ported under this subsection shall include—

11 “(A) the types and causes of errors in the  
12 provision of health care;

13 “(B) the impact of health care professional  
14 fatigue (including working hours and overtime),  
15 stress, and other workplace-related factors on  
16 patient safety;

17 “(C) staffing needs for health care organi-  
18 zations to provide quality health care;

19 “(D) training requirements for health care  
20 professionals to ensure that such professionals  
21 provide quality health care generally (such as  
22 continuous quality improvement training), in  
23 specific settings (such as the emergency room),  
24 and for specific practices (such as  
25 ultrasonography);

1 “(E) the use of intensivists and intensive  
2 care unit teams on patient outcomes;

3 “(F) the development of effective commu-  
4 nication methods and tools between disciplines  
5 to improve patient safety;

6 “(G) the use of interdisciplinary teams to  
7 improve patient safety;

8 “(H) the barriers to medical error reduc-  
9 tion strategies; and

10 “(I) other areas determined appropriate by  
11 the Secretary.

12 “(d) EVALUATIONS.—

13 “(1) GENERAL MEDICAL ERROR CONSIDER-  
14 ATIONS.—In carrying out subsection (b)(5) with re-  
15 spect to the evaluation of efforts to reduce medical  
16 errors and improve patient safety, the Director shall  
17 take into consideration—

18 “(A) the standardization of processes;

19 “(B) the reduction in system complexity;

20 “(C) human factors; and

21 “(D) the use of demonstration projects.

22 “(2) MEDICATION ERROR CONSIDERATIONS.—

23 In carrying out subsection (b)(5) with respect to the  
24 evaluation of efforts to reduce medication errors and

1 improve the safe use of medications, the Director  
2 shall take into consideration—

3 “(A) the computerization of the drug pre-  
4 scribing process;

5 “(B) effective prescriber and patient edu-  
6 cation;

7 “(C) the expanded and integrated use of  
8 pharmacists;

9 “(D) the use of bar codes on patient name  
10 bracelets and medications;

11 “(E) the controlled use of, and limited ac-  
12 cessibility to, highly toxic or hazardous drugs,  
13 such as potassium chloride, in health care orga-  
14 nizations;

15 “(F) the development and use of protocols  
16 for highly toxic or hazardous drugs and drugs  
17 with a narrow therapeutic range, such as writ-  
18 ten guidelines, checklists, pre-printed orders,  
19 double-checks, special packaging, special label-  
20 ing;

21 “(G) the use of pharmacy-based intra-  
22 venous admixture programs;

23 “(H) the standardization of drug storage  
24 locations, internal packaging or labeling;

1 “(I) the use of unit dose drug distribution  
2 systems;

3 “(J) the use of machine-readable labeling,  
4 such as a bar-coding system; and

5 “(K) the standardization of terminology,  
6 nomenclature (such as medication names), and  
7 abbreviations used in prescribing.

8 **“SEC. 924. NATIONAL PATIENT SAFETY REPORTING SYS-**  
9 **TEM.**

10 “(a) ESTABLISHMENT.—

11 “(1) IN GENERAL.—Not later than 1 year after  
12 the date of enactment of this part, the Director shall  
13 establish a National Patient Safety Reporting Sys-  
14 tem, to be headed by an administrator to be ap-  
15 pointed by the Director. The Director may contract  
16 with other organizations to carry out some or all of  
17 the components described in subsection (b).

18 “(2) VOLUNTARY SYSTEM.—The Voluntary Re-  
19 porting System shall be a voluntary medical error  
20 reporting system that collects voluntary reports on  
21 adverse safety events.

22 “(3) REPORTS CONCERNING FDA-REGULATED  
23 PRODUCTS.—With respect to adverse safety events  
24 that relate to products regulated by the Food and  
25 Drug Administration, the Director and the Commis-

1 sioner of the Food and Drug Administration, in con-  
2 sultation with the entities described in section  
3 922(c)(1), shall determine how reports under this  
4 section will be treated.

5 “(b) COMPONENTS.—The Voluntary Reporting Sys-  
6 tem shall—

7 “(1) encourage the voluntary, confidential re-  
8 porting of adverse safety events by any individual or  
9 entity, including health care organizations, health  
10 care professionals, and patients;

11 “(2) provide for the multi-disciplinary expert  
12 analysis of all reported adverse safety events;

13 “(3) provide for the clear identification of  
14 causes of medical errors;

15 “(4) develop effective, high-leverage patient  
16 safety solutions;

17 “(5) establish best practices, based on an anal-  
18 ysis of reports received, through the use of experts  
19 from multiple disciplines; and

20 “(6) provide for the widespread dissemination  
21 of information about medical errors and best prac-  
22 tices.

23 “(c) EXISTING REPORTING SYSTEMS.—In estab-  
24 lishing the Voluntary Reporting System, the Director shall  
25 consider—

1 “(1) whether to—

2 “(A) incorporate existing voluntary medical  
3 error reporting systems that are being imple-  
4 mented on the date of enactment of this part  
5 into the Voluntary Reporting System; or

6 “(B) complement the existing systems de-  
7 scribed in paragraph (1).

8 “(2) how to coordinate with mandatory sys-  
9 tems.

10 “(d) STANDARDS.—The Director shall develop stand-  
11 ards for the types of information to be reported to the  
12 Voluntary Reporting System.

13 “(e) REPORTING OF ADVERSE SAFETY EVENTS.—

14 “(1) WHO MAY REPORT.—Any individual or en-  
15 tity may report an adverse safety event to the Vol-  
16 untary Reporting System, including a health care or-  
17 ganization, a health care professional, or a patient.

18 “(2) REPORTING FORM.—

19 “(A) IN GENERAL.—The Director, in ac-  
20 cordance with subparagraph (B), shall develop  
21 the written and electronic forms to be used for  
22 submitting reports under this section.

23 “(B) REQUIREMENTS.—A form used for  
24 the reporting of information under this section  
25 shall contain standard minimum data fields—

1 “(i) for the identification of the re-  
 2 porting individual, except that nothing in  
 3 this section shall require a reporting indi-  
 4 vidual to provide such information if the  
 5 individual desires to remain anonymous;

6 “(ii) that provide for the identification  
 7 of the causes of the medical error de-  
 8 scribed in the report;

9 “(iii) that identify the relevant char-  
 10 acteristics about the health care organiza-  
 11 tion involved, including the location of the  
 12 organization (the city, State and urban or  
 13 rural nature of the location), the size of  
 14 the organization, and other characteristics  
 15 determined appropriate by the Director.

16 Such data may only be used in aggregate anal-  
 17 yses and may only be included in the National  
 18 Patient Safety Database if it cannot be used to  
 19 identify a specific health care organization,  
 20 health care professional, or patient.

21 “(3) SUBMISSION.—A reporting form may be  
 22 submitted under this section electronically, by mail,  
 23 by fax, or by telephone. The administrator shall es-  
 24 tablish a Post Office box, a toll-free fax number, a

1 toll-free telephone number, and an Internet website  
2 or e-mail address to receive reporting forms.

3 “(4) ADDITIONAL INFORMATION.—If the ad-  
4 ministrator of the Voluntary Reporting System de-  
5 termines that additional information is needed with  
6 respect to an adverse safety event report so that the  
7 report complies with the standards described in sub-  
8 section (d), the administrator may request such data  
9 from the reporting individual within 30 calendar  
10 days of receiving the report.

11 “(5) DE-IDENTIFICATION.—Upon a determina-  
12 tion by the administrator of the Voluntary Reporting  
13 System that no additional information is needed con-  
14 cerning a report under this section, or the expiration  
15 of the 30 calendar day-period beginning on the date  
16 on which the last submission of information for the  
17 report has occurred, whichever is earlier, the Vol-  
18 untary Reporting System shall remove all informa-  
19 tion that may be used to identify the reporting indi-  
20 vidual and all other persons and entities from the  
21 records of the Voluntary Reporting System. The ad-  
22 ministrator may establish a mechanism for notifying  
23 the reporting individual of such de-identification (if  
24 adequate contact information has been provided in

1 the report). Such mechanism shall be applied uni-  
2 formly.

3 “(6) LIMITATION.—No identifying information  
4 with respect to a reporting individual or other per-  
5 sons under this section may be disclosed to any  
6 other entity unless the adverse safety event involved  
7 in the report was a criminal act or an act related to  
8 an impaired health care professional or employee of  
9 a health care organization due to alcohol or sub-  
10 stance abuse. If the administrator of the Voluntary  
11 Reporting System determines that such an act has  
12 occurred, the administrator shall forward such re-  
13 port with the identifying information to the appro-  
14 priate regulatory or law enforcement entity.

15 “(f) ROOT CAUSE ANALYSIS.—

16 “(1) TECHNICAL ASSISTANCE.—The Director  
17 shall develop and disseminate model instructions and  
18 forms for conducting a root cause analysis that in-  
19 volves all relevant personnel and, upon request, pro-  
20 vide technical assistance.

21 “(2) BY DIRECTOR.—The Director may, upon  
22 request and for a fee to be determined by the Direc-  
23 tor to cover costs, conduct a root cause analysis on  
24 behalf of a health care organization.

25 “(g) ANALYSIS OF REPORTS.—

1           “(1) IN GENERAL.—The administrator of the  
2       Voluntary Reporting System shall ensure that anal-  
3       yses of data entered into the Voluntary Reporting  
4       System are reviewed by independent, multi-discipli-  
5       nary expert panels (as provided for in paragraph  
6       (2)) for each category of medical error that has been  
7       reported in order to objectively determine the causes  
8       of medical errors and develop evidence for best prac-  
9       tices to reduce and prevent such errors.

10           “(2) SELECTION OF PANELS.—A panel de-  
11       scribed in paragraph (1) shall be composed of ex-  
12       perts to be appointed by the Director in cooperation  
13       with the Director of the Centers for Disease Control  
14       and Prevention, the Commissioner of the Food and  
15       Drug Administration, the Director of the National  
16       Institutes of Health, the Secretary of Veterans Af-  
17       fairs, the Secretary of Defense, the Director of the  
18       National Academy of Sciences, as well as other in-  
19       terested parties, such as academic institutions, med-  
20       ical specialty societies, nursing and other health pro-  
21       fessional organizations, industry, labor, and con-  
22       sumer groups. Such panels shall be appointed in a  
23       manner that prevents conflicts of interests.

24           “(3) RESULTS.—The administrator of the Vol-  
25       untary Reporting System shall ensure that the re-

1       sults of the analyses conducted under this subsection  
2       are made available to the general public.

3       “(h) NATIONAL PATIENT SAFETY DATABASE.—

4               “(1) IN GENERAL.—The administrator of the  
5       Voluntary Reporting System shall ensure that all ad-  
6       verse safety event reports and analyses are cataloged  
7       in a database developed under the Voluntary Report-  
8       ing System. The information in the database shall  
9       use standard terminology and fields, to be developed  
10      by the Director, and be maintained in a manner that  
11      permits the information to be aggregated and com-  
12      pared across health care organizations and across  
13      States.

14             “(2) AVAILABILITY.—The database under para-  
15      graph (1) shall be designed in a manner so as to be  
16      accessible and easily usable by the general public.

17      “(i) RULE OF CONSTRUCTION.—Nothing in this sec-  
18      tion shall be construed to preempt or otherwise modify a  
19      Federal or State medical error or adverse safety event re-  
20      porting system in effect on, or established after, the date  
21      on which the Voluntary Reporting System is established.

22      **“SEC. 925. NATIONAL PATIENT SAFETY SURVEILLANCE SYS-**  
23                               **TEM.**

24      “(a) ESTABLISHMENT.—

1           “(1) IN GENERAL.—Not later than 1 year after  
2           the date of enactment of this part, the Director, in  
3           collaboration with the Director of the Centers for  
4           Disease Control and Prevention, the Commissioner  
5           of the Food and Drug Administration, the Adminis-  
6           trator of the Health Care Financing Administration,  
7           the Director of the National Institutes of Health,  
8           the Secretary of Veterans Affairs, and the Secretary  
9           of Defense, shall establish a National Patient Safety  
10          Surveillance System under which the Director will  
11          enter into voluntary agreements with a geographi-  
12          cally and institutionally diverse group of eligible en-  
13          tities to identify and monitor adverse safety events.  
14          The Director may contract with other organizations  
15          to carry out this section.

16          “(2) NUMBER AND TYPES OF ORGANIZA-  
17          TIONS.—In carrying out paragraph (1), the Director  
18          shall determine the number and types of health care  
19          organizations with whom to enter into agreements,  
20          as well as the types of adverse safety events the par-  
21          ticular health care organizations with which the Di-  
22          rector enters into an agreement should identify and  
23          the types of analyses that such organizations should  
24          perform.

1       “(b) ELIGIBILITY.—To be eligible to enter into an  
2 agreement under subsection (a) an entity shall—

3               “(1) be a health care organization; and

4               “(2) prepare and submit to the Director an ap-  
5 plication at such time, in such manner, and con-  
6 taining such information as the Director may re-  
7 quire.

8       “(c) SUBMISSION OF REPORTS.—

9               “(1) IN GENERAL.—A health care organization  
10 that enters into a voluntary agreement under sub-  
11 section (a) shall, with respect to such organization,  
12 submit reports of adverse safety events, or reports of  
13 specific types of adverse safety events if so pre-  
14 scribed by the agreement, and shall submit, if pre-  
15 scribed by the agreement, root cause analyses con-  
16 cerning such events (using standards developed by  
17 the Director), and corrective action plans to the Di-  
18 rector.

19               “(2) PROCESSING OF INFORMATION.—The Di-  
20 rector shall process the reports submitted under  
21 paragraph (1) in the same manner as reports are  
22 processed through the Voluntary Reporting System,  
23 including making data concerning such reports avail-  
24 able to the general public through the National Pa-  
25 tient Safety Database.

1           “(3) PROVISION OF FEEDBACK TO ORGANIZA-  
 2           TION.—The Director shall provide feedback con-  
 3           cerning adverse safety event reports directly to the  
 4           health care organizations that are participating in  
 5           this Surveillance System.

6           “(d) TECHNICAL ASSISTANCE.—The Director shall  
 7           provide participating health care organizations with tech-  
 8           nical support and may provide technology support, includ-  
 9           ing computer software and hardware.

10          “(e) RULE OF CONSTRUCTION.—Nothing in this sec-  
 11          tion shall be construed to preempt Federal or State sen-  
 12          tinel surveillance systems in effect on the date of enact-  
 13          ment of this part, or Federal or State sentinel surveillance  
 14          systems developed after such date of enactment.

15          **“SEC. 926. CENTERS OF PATIENT SAFETY IMPROVEMENT.**

16          “(a) ESTABLISHMENT.—The Director, in accordance  
 17          with section 923(b)(13), shall provide for the establish-  
 18          ment of Centers of Patient Safety Improvement to con-  
 19          duct, or facilitate the conduct of, research that focuses  
 20          on—

21                 “(1) particular types of medical errors (such as  
 22                 medication-related errors);

23                 “(2) medical errors in particular settings or  
 24                 clinical specialties (such as intensive care); and

1           “(3) types of interventions or strategies that  
 2           may be applied across many areas and settings (in-  
 3           cluding multi-disciplinary teams) to reduce medical  
 4           errors.

5           “(b) ELIGIBILITY.—To be eligible to be designated  
 6 as a Center of Patient Safety Improvement under sub-  
 7 section (a) an entity shall—

8           “(1) be a health care organization or an applied  
 9           research entity; and

10           “(2) prepare and submit to the Director an ap-  
 11           plication at such time, in such manner, and con-  
 12           taining such information as the Director may re-  
 13           quire including a description of the research to be  
 14           conducted.

15           “(c) ACTIVITIES.—A Center of Patient Safety Im-  
 16           provement shall—

17           “(1) conduct state-of-the-art research—

18           “(A) to increase the awareness of health  
 19           care organizations, health care professionals,  
 20           and the general public concerning—

21           “(i) medical errors;

22           “(ii) lessons learned; and

23           “(iii) best practices;

24           “(B) to better understand the causes of  
 25           medical errors;

1           “(C) to develop and assess best practices  
2           to improve patient safety;

3           “(D) to evaluate outcomes measures for  
4           accuracy and reliability in assessing the impact  
5           of best practices on patient safety; and

6           “(E) to improve patient safety by pre-  
7           venting medical errors and increasing the use of  
8           best practices; and

9           “(2) conduct such other activities as the Sec-  
10          retary determines to be appropriate.

11   **“SEC. 927. CONFIDENTIALITY.**

12          “(a) INFORMATION PRIVILEGED AND CONFIDEN-  
13   TIAL.—Notwithstanding any other provision of law and  
14   except as provided in subsection (c), information developed  
15   in connection with the Voluntary Reporting System or the  
16   Surveillance System (including any root cause analyses of  
17   reported adverse safety events and the corrective actions  
18   taken in response to such events), as well as the fact that  
19   a report was submitted to either System, shall be privi-  
20   leged and confidential and shall not be susceptible to legal  
21   process or otherwise disclosed in connection with any civil,  
22   criminal, or administrative proceeding under Federal or  
23   State law, or subject to disclosure under the Freedom of  
24   Information Act under section 552 of title 5, United  
25   States Code, or similar State laws.

1       “(b) APPLICATION OF SECTION.—Subsection (a)  
2 shall apply to information, but not facts, that is in the  
3 custody of a health care professional, a health care organi-  
4 zation, or an employee of a health care organization, or  
5 that is transferred to an individual, entity, or agency pur-  
6 suant to this part, that was created for submission to the  
7 Voluntary Reporting System or the Surveillance System.

8       “(c) EXCEPTION.—Subsection (a) shall not apply  
9 to—

10           “(1) information that is false if the individual  
11 providing the information to the Voluntary Report-  
12 ing System or the Surveillance System knew that the  
13 information was false;

14           “(2) information that is the custody of a health  
15 care professional or health care organization that  
16 has been developed or maintained separately from  
17 the process by which the professional or organization  
18 develops information for submission to the Voluntary  
19 Reporting System or the Surveillance System, such  
20 as patient medical records, except that this para-  
21 graph shall not be construed to limit other privileges  
22 that may be available under Federal or State law;

23           “(3) nonidentifiable information entered into  
24 the National Patient Safety Database;

25           “(4) a criminal act; and

12       “(e) **LIABILITY.**—Nothing in this section shall be  
13 construed as limiting the liability of an individual, entity,  
14 or agency for damages relating to the occurrence of an  
15 adverse safety event.

22 “SEC. 928. PROTECTIONS FOR PATIENT SAFETY REPORT-  
23 ING.

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1 against a health care worker with respect to compensation,  
2 terms, conditions, or privileges of employment, because the  
3 health care worker in good faith—

4 “(1) provides information relating to a medical  
5 error to the Reporting System or the Surveillance  
6 System;

7 “(2) discloses information relating to the care,  
8 services, or conditions affecting one or more patients  
9 to an appropriate public regulatory agency, an ap-  
10 propriate private accreditation body, or the appro-  
11 priate management personnel of the health care or-  
12 ganization; or

13 “(3) initiates, cooperates, or otherwise partici-  
14 pates in an investigation or proceeding by such an  
15 agency with respect to such care, services, or condi-  
16 tions.

17 “(b) REQUIREMENT OF GOOD FAITH.—For purposes  
18 of subsection (a), a health care worker is considered to  
19 be acting in good faith with respect to disclosures de-  
20 scribed in subsection (a) if, with respect to the information  
21 disclosed—

22 “(1) the disclosure is made on the basis of per-  
23 sonal knowledge and is consistent with that degree  
24 of learning and skill ordinarily possessed by health

1 care workers with the same experience, licensure, or  
2 certification;

3 “(2) the worker reasonably believes the infor-  
4 mation to be true;

5 “(3) the information evidences a medical error,  
6 a violation of a law, rule, or regulation, of an appli-  
7 cable accreditation standard, or of a generally recog-  
8 nized professional or clinical standard, or that a pa-  
9 tient is in imminent hazard of loss of life or serious  
10 injury; and

11 “(4) pursuant to disclosures or reports made in  
12 accordance with paragraphs (2) and (3) of sub-  
13 section (a) and subject to paragraphs (2) and (3) of  
14 subsection (c), the worker has followed reasonable  
15 internal procedures of the health care organization  
16 established for the purpose of addressing quality  
17 concerns before making the disclosures.

18 “(c) EXCEPTION AND SPECIAL RULE.—

19 “(1) GENERAL EXCEPTION.—Subsection (a)  
20 shall not be construed to protect disclosures that  
21 would violate Federal or State laws or diminish or  
22 impair the rights of any person to the continued pro-  
23 tection of confidentiality of communications provided  
24 by such laws.

1           “(2) NOTICE OF INTERNAL PROCEDURES.—

2           Paragraph (4) of subsection (b) shall not apply to  
3           a disclosure unless the internal procedures involved  
4           are reasonably expected to be known to the health  
5           care worker involved. For purposes of this para-  
6           graph, a health care worker is reasonably expected  
7           to know of internal procedures if those procedures  
8           have been made available to the worker through dis-  
9           tribution or posting.

10           “(3) INTERNAL PROCEDURE EXCEPTION.—

11           Paragraph (4) of subsection (b) also shall not apply  
12           to a disclosure if—

13                   “(A) the disclosure relates to an imminent  
14                   hazard of loss of life or serious injury to a pa-  
15                   tient;

16                   “(B) the disclosure is made to an appro-  
17                   priate private accreditation body pursuant to  
18                   disclosure procedures established by the body;  
19                   or

20                   “(C) the disclosure is in response to an in-  
21                   quiry made in an investigation or proceeding of  
22                   an appropriate public regulatory agency and the  
23                   information disclosed is limited to the scope of  
24                   the investigation or proceeding.

1       “(d) NOTICE.—A health care organization shall post  
 2 a notice, to be provided or approved by the Secretary of  
 3 Labor, setting forth excerpts from, or summaries of, the  
 4 pertinent provisions of this section and information per-  
 5 taining to enforcement of such provisions.

6       “(e) HEALTH CARE WORKER DEFINED.—For the  
 7 purposes of this subsection, the term ‘health care worker’  
 8 means an employee of the health care organization as well  
 9 as an employee of a subcontractor or independent con-  
 10 tractor who provides health care services, treatment, as-  
 11 sistance with daily living activities, or medications to pa-  
 12 tients. Such term includes physician, intern, resident,  
 13 nurse, nurse’s aide, and laboratory technician.”.

14 **“SEC. 929. ENFORCEMENT BY THE SECRETARY OF LABOR.**

15       “(a) FILING OF COMPLAINT.—A health care profes-  
 16 sional who believes that he or she has been discharged or  
 17 otherwise discriminated against in violation of section  
 18 928(a) may, within 180 days after the date on which the  
 19 violation is alleged to have occurred, file a complaint with  
 20 the Secretary of Labor alleging a violation of such section.

21       “(b) PROCEDURES.—Upon the filing of a complaint  
 22 under subsection (a), the Secretary shall—

23               “(1) notify the health care organization named  
 24       in the complaint; and

1           “(2) investigate, afford an opportunity for a  
2       hearing, and issue findings with respect to the com-  
3       plaint using the same procedures used for com-  
4       plaints filed under section 31105(b) of title 49,  
5       United States Code.

6 Appeals from orders issued under this section, as well as  
7 civil actions to enforce such orders, shall be brought pur-  
8 suant to the procedures contained in section 31105(b) of  
9 title 49, United States Code.

10       “(c) DETERMINATIONS.—If, in response to a com-  
11       plaint filed under subsection (a), the Secretary of Labor  
12       determines that a violation of section 928(a) may have oc-  
13       curred, the Secretary shall order, as appropriate—

14           “(1) that the health care organization reinstate  
15       the health care professional to his or her former po-  
16       sition together with the compensation (including  
17       back pay), terms, conditions and privileges of the po-  
18       sition;

19           “(2) compensatory damages; and

20           “(3) exemplary damages.

21       “(d) COSTS AND EXPENSES.—Upon the issuance of  
22 an order under subsection (c), the Secretary of Labor may  
23 assess against the health care organization involved a sum  
24 equal to the costs and expenses (including attorney’s fees  
25 and expert witness fees) reasonably incurred by the health

1 care professional, as determined by the Secretary, in  
 2 bringing the complaint, including costs and expenses in-  
 3 curred as part of an appeal.

4 **“SEC. 930. REPORTS.**

5 “Not later than 1 year after the establishment of the  
 6 Center, and annually thereafter, the Director shall pre-  
 7 pare, submit to Congress, and make available to health  
 8 care organizations, health care professionals, and the gen-  
 9 eral public, a report on the progress made in improving  
 10 patient safety. Such report shall include the recommenda-  
 11 tions of the Director for modifications—

12 “(1) in the activities of the Agency for  
 13 Healthcare Research and Quality; and

14 “(2) in other Federal or State programs, and in  
 15 the activities of accrediting organizations, health  
 16 care professional associations, group health plan  
 17 purchasers, and health care organizations;  
 18 to improve patient safety.

19 **“SEC. 930A. AUTHORIZATION OF APPROPRIATIONS.**

20 “There is authorized to be appropriated to carry out  
 21 this part—

22 “(1) \$50,000,000 for fiscal year 2001, of which  
 23 \$25,000,000 shall be made available to fund the Vol-  
 24 untary Reporting System and the Surveillance Sys-  
 25 tem;

1           “(2) \$100,000,000 for fiscal year 2002, of  
2           which \$35,000,000 shall be made available to fund  
3           the Voluntary Reporting System and the Surveil-  
4           lance System;

5           “(3) \$150,000,000 for fiscal year 2003, of  
6           which \$50,000,000 shall be made available to fund  
7           the Voluntary Reporting System and the Surveil-  
8           lance System;

9           “(4) \$175,000,000 for fiscal year 2004, of  
10          which \$60,000,000 shall be made available to fund  
11          the Voluntary Reporting System and the Surveil-  
12          lance System; and

13          “(5) \$200,000,000 for fiscal year 2005, of  
14          which \$75,000,000 shall be made available to fund  
15          the Voluntary Reporting System and the Surveil-  
16          lance System.”.

17 **SEC. 4. APPLICATION TO DEPARTMENT OF HEALTH AND**  
18 **HUMAN SERVICES PROGRAMS.**

19          (a) IN GENERAL.—The Secretary of Health and  
20 Human Services shall—

21               (1) develop a process for determining which evi-  
22               dence-based best practices disseminated by the Di-  
23               rector under part C of title IX of the Public Health  
24               Service Act (as added by section 3) should be ap-  
25               plied to health care organizations, health care pro-

1       professionals, and any other entity or individual who  
2       participates in a Federally funded health care pro-  
3       gram that is under the authority of the Secretary;

4           (2) take reasonable steps (including revising  
5       agreements with utilization and quality control peer  
6       review organizations) as may be appropriate to bring  
7       about the implementation of the best practices se-  
8       lected by the Secretary using the process developed  
9       under paragraph (1);

10          (3) enter into agreements with utilization and  
11       quality control peer review organizations, accrediting  
12       organizations, and State agencies for such organiza-  
13       tions to provide, upon request, technical assistance,  
14       expert advice, and education to entities and individ-  
15       uals described in paragraph (1) regarding the best  
16       practices made applicable to such entities and indi-  
17       viduals under such paragraph, as well as how to per-  
18       form root cause analyses;

19          (4) take reasonable actions as may be appro-  
20       priate to bring about the implementation of a pa-  
21       tient safety program in each participating health  
22       care organization that includes—

23           (A) a process and standards for the inter-  
24       nal identification of adverse safety events;

1 (B) a process and standards for per-  
2 forming internal root cause analyses of adverse  
3 safety events that caused or could have caused  
4 serious injury or death;

5 (C) a process for developing an internal  
6 corrective action plan for adverse safety events  
7 identified under subparagraph (B);

8 (D) a process for informing health care  
9 professionals who are employed by the health  
10 care organization of—

11 (i) evidence-based best practices dis-  
12 seminated by the Director;

13 (ii) other methods to improve patient  
14 safety; and

15 (iii) other patient safety-related  
16 issues; and

17 (E) a process for informing the chief ad-  
18 ministrative officer, other senior management  
19 officials, and the health care professional em-  
20 ployees of the health care organization of ad-  
21 verse safety events evaluated under subpara-  
22 graph (B), and the corrective action plans im-  
23 plemented under subparagraph (C); and

1           (5) identify increased use of autopsies as one of  
 2           the quality improvement goals of the Secretary’s  
 3           quality improvement programs.

4           (b) AVAILABILITY OF DATA.—As a condition of  
 5           maintaining its deemed status with the Secretary of  
 6           Health and Human Services relating to any Federally  
 7           funded health care program that is under the authority  
 8           of the Secretary, the Joint Commission on Accreditation  
 9           of Health Care Organizations shall agree to make de-iden-  
 10          tified data received by the Joint Commission through its  
 11          Sentinel Event Program available to the Director.

12 **SEC. 5. APPLICATION TO THE FEDERAL EMPLOYEES**  
 13 **HEALTH BENEFITS PROGRAM.**

14          Chapter 89 of title 5, United States Code is  
 15          amended—

16               (1) in section 8902—

17                       (A) in subsection (e), by striking “(e) The”  
 18                       and inserting “(e)(1) Subject to subsection (p),  
 19                       the”; and

20                       (B) by adding at the end the following:

21               “(p) The Director of the Office of Personnel Manage-  
 22          ment shall—

23                       “(1) develop a process for determining which  
 24                       evidence-based best practices disseminated by the  
 25                       Director of the Agency for Healthcare Research and

1       Quality under part C of title IX of the Public Health  
2       Service Act should be applied to health benefits  
3       plans described in section 8903 or 8903a as pur-  
4       chasing standards;

5               “(2) develop measures to rate such plans on pa-  
6       tient safety improvement activities identified by the  
7       Director of the Office of Personnel Management;  
8       and

9               “(3) rate such plans using the measures devel-  
10      oped under paragraph (2).”; and

11              (2) in section 8907(a), by adding at the end the  
12      following: “Such information shall include the rating  
13      (based on measures developed by the Director of the  
14      Office of Personnel Management) for each plan ap-  
15      proved for enrollees under this title.”.

○